



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 20, 2005

Mr. Edward John Allera
Mr. Theodore Sullivan
Buchanan Ingersoll P. C.
1776 K Street, N.W.
Suite 800
Washington, DC 20006

FILE COPY

Dear Mr. Allera and Mr. Sullivan:

Your petition on behalf of Savient Pharmaceuticals, Inc. requesting that the Food and Drug Administration verify the scope of Savient's three year exclusivity for geriatric dosing information and geriatric studies data for its Oxandrin drug product, was received by this office on 09/19/2005. It was assigned docket number 2005P-0383/CP 1 and it was filed on 09/20/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0383

ACK1